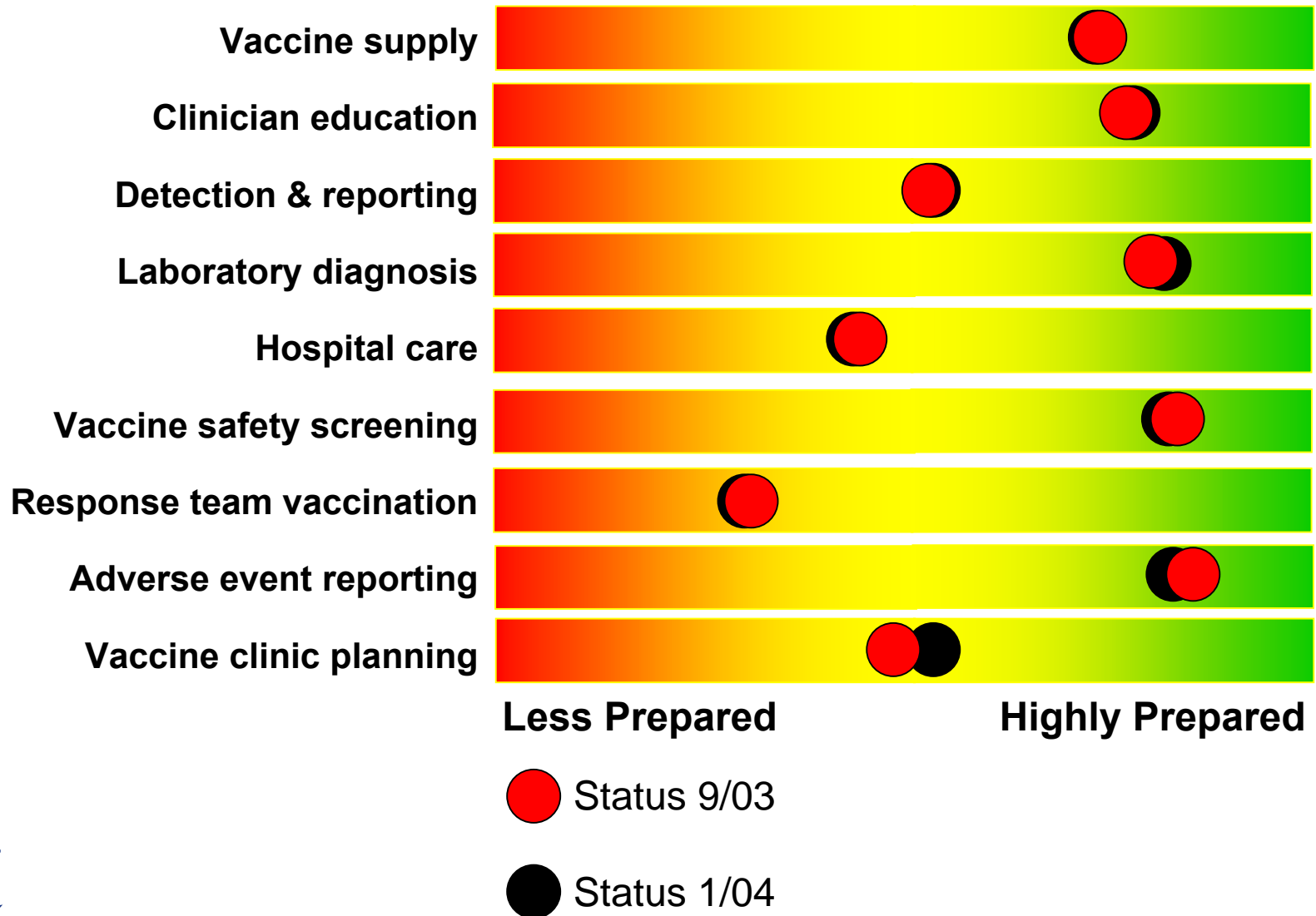




Update on Smallpox Readiness

Secretary's Council on Public Health Preparedness
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Vaccination Summary 1/24/03 - 12/31/03

- **Number vaccinated: 39,213 (+305 since 11/30/03)**
 - Public health: 12,131
 - Health care: 25,076 (Hospitals participating 2,255)
 - Other: 2,006
- **Vaccine in the field in unopened vials = 184,800 (64,858 expired in open vials)**
- **Female: 65%**
- **Primary vaccinees: 25%**
- **Age distribution: 80% ≥ 40 years**
- **Take response**
 - All vaccinees: 92%
 - Primary vaccinees: 90.3%
 - Revaccinees: 92.5%

- **Approximately 2.4 serious adverse events/1,000 doses administered**
- **No contact transmission in civilian program**
- **A causal association between smallpox vaccination and myo/pericarditis appears likely**
 - Based primarily on DoD data; evidence is less clear in civilian vaccinees - likely due to differences in the 2 populations (e.g., age, gender, prior vaccination status, case ascertainment) rather than status as military or civilian personnel.

Cardiac events

- **Ischemic Events (n=8)**
- **Myo/pericarditis (n=22)**
 - Historically only rare reports in US
 - Case reports in Europe and Australia
 - Different vaccine strain
- **Dilated cardiomyopathy (n=2)**

Early Pregnancy Outcomes of Women Exposed to Smallpox Vaccine

(Preliminary Findings)

- **12 civilian women inadvertently exposed to the smallpox vaccine in pregnancy:**
 - 10 vaccine recipients
 - 2 close contacts of vaccine recipients
- **Age distribution:**
 - Range: 26 – 38 years
 - Mean: 31 years
- **Vaccination status:**
 - 3 out of 10 had received the vaccine previously
 - Vaccination status unknown for contacts

- **Continue educational and screening efforts and quantify impact**
- **Continue surveillance and pregnancy registry for known and unexpected serious adverse events**
- **Complete investigation and follow-up of vaccinees with cardiac events**

Public complacency:

- Smallpox threat perceived to be near zero since end of the Iraq war
- Smallpox preparation perceived to be low priority or not worth the risk

Public health and hospital workforce that is:

- Not fully engaged
- Skeptical about the credibility of the smallpox threat
- Confused about vaccination risks and available protections
- Finding it problematic to separate smallpox from other threats

Vaccination of citizens who insist on being vaccinated:

- Licensed vaccine in 2004
- Current access limited to clinical trials
- No other program initiated
- Demand for vaccination is very small

\$100M (one-time) supplement for Smallpox Preparedness in FY03

Smallpox Readiness Elements

- Early detection, reporting, isolation, and treatment of cases
- Rapid investigation and prophylaxis of contacts
- Mass vaccination such that the entire population is vaccinated within 10 days of first confirmed case (NYS and WA models)
- Assure critical messages and materials are provided to the public before, during, and after response
- Laboratory capacity to confirm smallpox disease and rule-out other rash illnesses
- Management of vaccine supplies
- Drills and exercises to test proficiency
- Data and information management and
- Voluntary vaccination and training of key responders prior to an outbreak

Action Plan -- HHS/CDC will:

- **Increase national awareness of threat and safety of vaccine**
 - Develop and implement a comprehensive communication strategy (JAN 2004)
 - Discuss progress: NYS, NYC, WA, FL, TX, CA (NOV 03 – Feb 04)
 - Provide State and local health officials with updated smallpox threat briefing (?)
 - Outline social and economic consequences of a smallpox attack (SPRING 2004)
- **Measure State and local preparedness**
 - Link to national emergency public health preparedness performance measures (WORK IN PROGRESS)
 - Build federal (standards-based) exercise scenarios and test (Late 2004)
- **Add smallpox and bioterrorism preparedness standards into hospital accreditation process (WORKING WITH HRSA)**
- **Other options to deliver 10-day vaccination strategies (i.e., engage VA and DoD to supplement preparedness and response capacity)**
- **Develop options to make vaccine available to citizens who insist on vaccination (WAITING FOR ACAMBIS VACCINE) – Zero demand for the vaccine based on canvassing the states)**

Discussion
